

REMARKS

This responds to the Final Office Action dated June 5, 2007 (hereinafter “Office Action”). Claim 23 is currently amended and fully supported by the application as filed, such as at [0023] and FIG. 3. Claims 15-20 were previously canceled without prejudice or disclaimer. Claims 4, 8-14, 22, and 27-42 have been previously withdrawn, but should be considered upon the allowance of generic claim 1. Accordingly, claims 1-3, 5-7, 21 and 23-26 are currently pending in this patent application.

Applicant hereby respectfully requests further examination and reconsideration of this application in view of the foregoing claim amendment and following remarks.

§112 Rejection of the Claims

1. Claim 23 was rejected under 35 USC § 112 for failing to comply with the written description requirement. Applicant has amended claim 23 to satisfy the issue noted in the Office Action. Reconsideration and withdrawal of this rejection is respectfully requested.

§102 Rejection of the Claims

2. Claims 1-3, 5-7 and 23-24 were rejected under 35 USC § 102(e) as being anticipated by Gardeski et al. (US Patent No. 7,130,700) (hereinafter “Gardeski”). Applicant respectfully traverses on the ground that Gardeski fails to recite each element of the claims.

Claim 1:

Claim 1 recites an implantable lead comprising “one or more fillers disposed within [a] tubular lead body, the one or more fillers are disposed adjacent to [an] insulated at least one conductor and include one or more recesses; and the at least one conductor is disposed outside the one or more recesses.” Applicant cannot find in Gardeski any recitation of a lead comprising a conductor that is disposed outside a recess portion of a lead body filler. Rather, Gardeski recites a lead having elongated members, such as conductors, which are received by one of a plurality of recesses or lumens in a filler. For example, Gardeski expressly states:

The first tubular member and the second tubular member form a plurality of lumens extending from a proximal end through the distal end of the multibody lumen, the plurality of lumens receiving elongated members therein.

(Gardeski at col. 3, lns. 35-40; col. 3, lns. 52-54.)

During assembly, conductors may be laid in grooves formed between pairs of outward radiating splines on the inner insulating member.

(Gardeski at col. 6, lns. 7-10.)

[A] splined lead body according to the present invention may be provided having a corresponding number of mated splines for forming two, three or more lumens corresponding to the number of conductors required.

(Gardeski at col. 14, lns. 42-45.)

According to the present invention, each of conductors 150-156 are positioned within a respective slot portion 119 of lumens 140a-d formed by inner insulating member 134.

(Gardeski at col. 15, lns. 61-63.) In agreement with these recitations of Gardeski, the Office Action appears to recognize that the conductors of Gardeski are disposed only in recess portions of the asserted filler. (*See* Office Action at 5, stating elements “119” and “121” are interpreted as recesses and element “150”, an insulated conductor, is disposed in recess “121”.) According to the Federal Circuit, “[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303, 313 (Fed. Cir. 1983). Because Gardeski does not recite a conductor that is disposed outside the recesses of a lead body filler, as recited in Applicant’s claim 1, Gardeski does not anticipate claim 1.

For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 1. Claims 2-3, 5-7, 21, and 23-26 are dependent on claim 1 and are patentable over Gardeski for the reasons stated above, in addition to the elements in such claims.

Claim 6:

Additionally, regarding claim 6, Applicant cannot find in Gardeski any recitation of one or more fillers “generally C-shaped,” as recited in such claim. The Office Action asserts that Gardeski recites a filler including “one or more generally C-shaped recesses,” but not that the

filler itself is generally C-shaped, as claimed by Applicant. (Office Action at 5.) Regarding the shape of the filler, Gardeski expressly states:

Inner insulation member 14 is . . . preferably, a generally tubular structure having at least one generally central, inner lumen 22 through which a medical device or therapy may be delivered.

(Gardeski at col. 7, lns. 36-39.)

Because Gardeski does not recite one or more fillers having a generally C-shape, as recited in Applicant's claim 6, Gardeski does not anticipate such claim. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 6.

Claim 23:

Additionally, regarding claim 23, Applicant cannot find (nor has the Office Action identified) in Gardeski any recitation of one or more fillers "radially extend[ing] from a first end to a second end, and at least a first and a second insulated cable conductor [being] disposed distally between the first and second ends," as recited in such claim.

For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 23.

3. Claims 1-3, 5-7 and 23-25 were rejected under 35 U.S.C. § 102(e) as being anticipated by Cross, Jr. et al. (US Patent No. 5,935,159) (hereinafter "Cross, Jr."). Applicant respectfully traverses on the ground that Cross, Jr. fails to recite each element of the claims.

Claim 1:

Claim 1 recites an implantable lead comprising "one or more fillers disposed within [a] tubular lead body, the one or more fillers are disposed adjacent to [an] insulated at least one conductor and include one or more recesses; and the at least one conductor is disposed outside the one or more recesses." Applicant cannot find in Cross, Jr. any recitation of a lead comprising a conductor that is disposed outside a recess portion of a lead body filler. Rather, Cross, Jr. recites a lead filler with longitudinally extending groove recesses in which conductors are located. For example, Cross, Jr. expressly states:

The lead body is formed of separate parts including an extruded core or strut member which is provided with longitudinally extending grooves in which conductors may be located and an outer tubing member, surrounding the core.

(Cross, Jr. at col. 1, lns. 21-25; *see also* Abstract.)

FIG. 3 shows a cross-section through a lead body employing the core 102 illustrated in FIG. 2. An outer, insulative tube 100 is shown surrounding core 102, defining four lumens in which four insulated conductors 104, 106, 108 and 110 are located.

(Cross, Jr. at col. 2, lns. 52-56.) Because Cross, Jr. does not recite a conductor that is disposed outside the recesses of a lead body filler, as recited in Applicant's claim 1, Cross, Jr. does not anticipate such claim.

For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 1. Claims 2-3, 5-7, 21, and 23-26 are dependent on claim 1 and are patentable over Cross, Jr. for the reasons stated above, in addition to the elements in such claims.

Claims 2-3:

Additionally, regarding claims 2-3, Applicant cannot find in Cross, Jr. any recitation of one or more fillers including one or more recesses wherein "the one or more recesses include compression features," as recited in claim 2, or wherein "the compression features include compression waves," as recited in claim 3. The Office Action has previously asserted that the "radially extending portions (180, 182, 184, 186)" of Cross, Jr. comprise the compression features and the longitudinally extending grooves "(190, 192, 194, 196)" of Cross, Jr. comprise the compression waves. (Office Action dated July 24, 2006 at page 3). However, Cross, Jr. expressly recites:

[L]ongitudinally extending grooves in which conductors are located and an outer tubular member, encasing the core and conductors . . . [t]ube 100 has an inner diameter approximately equal to the outer diameter of core 102.

(Cross, Jr. at Abstract; col. 3, lines 25-26). Applicant submits the disposition of the conductors into the grooves of Cross, Jr. in conjunction with approximately equal inner tube diameter and outer core diameter does not allow for the presence of compressive recesses (e.g., compression waves) as claimed.

Because each element of Applicant's claims 2-3 cannot be found in Cross, Jr., Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claims 2-3.

Claim 6:

Additionally, regarding claim 6, Applicant cannot find in Cross, Jr. any recitation of one or more fillers "generally C-shaped," as recited in such claim. The Office Action asserts that Cross, Jr. recites a filler including "one or more generally C-shaped recesses," but not that the filler itself is generally C-shaped, as claimed by Applicant. (Office Action at 5.) Regarding the shape of the filler, Cross, Jr. expressly states:

Core 102 is provided with four radially extending portions 180, 182, 184 and 186 which extend longitudinally along the length of the core.

(Cross, Jr. at col. 2, lines 35-36). Applicant submits the four radially extending core portions of Cross, Jr. result in a core that is generally X-shaped.

Because Cross, Jr. does not recite on or more fillers having a generally C-shape, as recited in Applicant's claim 6, Cross, Jr. does not anticipate such claim. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 6.

Claim 23:

Additionally, regarding claim 23, Applicant cannot find (nor has the Office Action identified) in Cross, Jr. any recitation of one or more fillers "radially extend[ing] from a first end to a second end, and at least a first and a second insulated cable conductor [being] disposed distally between the first and second ends," as recited in such claim.

For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 23.

§103 Rejection of the Claims

4. Claim 21 was rejected under 35 USC § 103(a) as being unpatentable over Gardeski. Applicant respectfully requests reversal of this rejection on the ground that there is no *prima facie* case of obviousness.

Claim 21:

Claim 21 recites an implantable lead wherein “a flexibility of the one or more fillers is greater than a flexibility of the tubular body.” The Office Action expressly admits that Gardeski fails to recite such elements, but asserts that modifying the inner insulating member as taught by Gardeski to have a flexibility greater than a flexibility of the tubular body would have been “an obvious design choice.” (Office Action at 6.) Applicant submits that such assertion *prima facie* fails to satisfy the requirements of 35 USC § 103, as Gardeski apparently teaches against the claimed subject matter. For example, Gardeski expressly states:

For example, in one embodiment for providing enhanced torque transfer properties, inner insulating member 134 is formed from a polyketone, such as polyaryletherketone, available commercially under the tradename PEEK-Op-tima®, from Inyibio™, or polyetheretherketone available from Victrex-USA. The outer insulating member 132 may be formed from silicone.

(Gardeski at col. 15, Ins. 1-7; *see also* col. 10, ln. 67 – col. 11, ln. 2, implying that enhanced torque is provided at the expense of reduced flexibility). In other words, and in contrast to Applicant’s claim 21, Gardeski recites an inner filler member having enhanced torque transfer and reduced flexibility properties.

Because Gardeski teaches against the asserted obvious design choice, such assertion is improper and fails to *prima facie* establish all elements recited in Applicant’s claim 21. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 21.

5. Claim 26 was rejected under 35 USC § 103(a) as being unpatentable over Cross, Jr. in view of Gardeski. Applicant respectfully requests reversal of this rejection on the ground that there is no *prima facie* case of obviousness.

The proposed combination of Cross, Jr. and Gardeski is improper and fails to establish all elements recited in Applicant’s claim 26. Claim 26 recites an implantable lead including a coiled conductor and at least one cable conductor wherein “an outer surface portion of the at least one cable conductor contact[s] an outer surface portion of the coiled conductor.” The Office Action admits that Cross, Jr. does not recite an outer surface portion of a cable conductor contacting an outer surface portion of a coiled conductor. (Office Action at 7.) Instead, the Office Action

attempts to rely on Gardeski to establish this missing cable-coiled conductor contacting arrangement. (*Id.*) However, Gardeski actually is directed to leads having a coiled conductor(s) which is/are isolated from cable conductors via insulative arm portions of a lead body filler. For example, Gardeski expressly states:

In FIG. 8, lumens 140*a*, 140*c* and 140*d* carry insulated conductors 150, 152, and 154 . . . [l]umen 140*b* carries a conductor 156, which may be provided as a multifilar coiled conductor.

(Gardeski at col. 15, lns. 13-20; FIG. 8.)

According to the present invention, each of conductors 150-156 are positioned within a respective slot portion 119 of lumens 140*a-d* formed by inner insulating member 134 . . . as a result, simultaneously capturing each conductor within a respective lumen.

(Gardeski at col. 15, ln. 61-col. 16, ln. 1.) In other words, and in contrast to Applicant's claimed combination, Cross, Jr. in view of Gardeski recite a conductor arrangement in which an outer surface portion of a cable conductor does not contact an outer surface portion of a coiled conductor. According to the Federal Circuit, motivation to combine references is lacking when the references teach away from the claimed combination. (*See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986)(A reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered); *see also* Office Action at 2.) Because the combination of Cross, Jr. and Gardeski teach away from the Applicant's claimed combination of an outer surface portion of a cable conductor contacting an outer surface portion of a coiled conductor, such combining of references is improper and fails to establish all elements recited in claim 26.

For at least this reason, Applicant respectfully requests reconsideration and withdrawal of this basis of rejection of claim 26.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited and encouraged to telephone Applicant's attorneys Catherine I. Klima-Silberg at (612) 359-3276 or Gregory W. Smock at (612) 373-6956 to facilitate prosecution of this application.

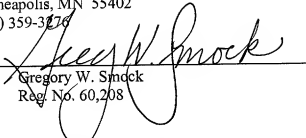
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Respectfully submitted,

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Date August 6, 2007

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